

EXHIBIT 106

SOP #:	SOP- 8489
TITLE:	Suspicious Order Monitoring – DEA Order Holds – Locations Other Than New Britain, PA and North Wales, PA

1. PURPOSE

To specify procedures for reviewing, investigating and releasing DEA Order Holds for controlled substances and the reporting of Suspicious Orders to the DEA.

2. SCOPE

These procedures apply to the following TEVA Pharmaceuticals personnel:

	CIMA Labs	Salt Lake City, UT	Cincinnati, OH	Malvern, PA	Sellersville, PA	West Chester, PA	Pomona, NY	Forest, VA
DEA Compliance & Diversion Operations	X	X	X	X	X	X	X	X

3. SUMMARY OF REVISIONS

n/a

4. REFERENCES

21 CFR 1301.74(b) states that “the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

5. DEFINITIONS

DEA: Abbreviation for the Drug Enforcement Administration

SOM: Abbreviation for Suspicious Order Monitoring

SUSPICIOUS ORDERS: Includes, but not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.



Page 1 of 3

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6. PROCEDURE

Responsibility

Action

6.1

Order Monitoring

DEA Compliance

6.1.1

Transfers of product from these locations are exclusively intra-site, intra-company or to clinical or analytical testing labs. The locations specified within the scope of this SOP do not accept unsolicited purchase requests or orders for any controlled substance product from any customer location. Transfers are initiated by TEVA personnel in order to have products tested analytically or clinically, or for intra-site transfer for sale at other locations.

6.1.2

Due to the nature of the development business there are limited purchase orders or purchase requests to trend by size or frequency using traditional statistical systems. In the event that any of these locations were to receive an unsolicited order for a controlled substance from any existing or potential customer, all information about the attempted order will be given to TEVA SOM Manager or designee for further investigation.

7. ATTACHMENTS

Title 21, Code of Federal Regulations, Section 1301.74(b);

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QUIZ

- Locations specified by this SOP accept unsolicited orders for controlled substances.

True

False
- Transfers are initiated by TEVA personnel in order to have products tested analytically or clinically, or for intra-site transfer for sale at other locations.

True

False
- Unsolicited orders for controlled substances from any existing or potential customer will be given to TEVA SOM Manager or designee for further investigation.

True

False

Written/Revised By:	Jason Gardner/Joseph Tomkiewicz	Effective Date:	10/1/15
Approved By:	Colleen McGinn	Revised Date:	N/A
Approver Signature:			